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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/813,249

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Anna Depicker

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EXAMINER

MEHTA, ASHWIN D

ART UNIT

PAPER NUMBER

1638

NOTIFICATION DATE

DELIVERY MODE

05/09/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/813,249	Applicant(s) DEPICKER ET AL.	
	Examiner Ashwin Mehta	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 14-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The papers filed February 7, 2008 were entered. The recitations “means for targeting the recombinant gene for posttranscriptional gene silencing” and “means for targeting the target gene for posttranscriptional gene silencing” in new claim 18 are being treated under 35 U.S.C. 112, 6th paragraph.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The objection to claim 1 is withdrawn in light of its amendment.
4. The rejection of claims 1-10 under 35 U.S.C. 112, 2nd paragraph, is withdrawn in light of the claim amendments. Regarding claims 3-6, Applicants’ argument in reference to *KCJ Corp. v. Kinetic Concepts, Inc.* was found persuasive (response, page 8).

Priority

5. A certified copy of EPO 01203760.2 has been received. However, this does not perfect the conditions for receiving the benefit of its filing date because a certified copy of PCT/EP02/11188 has not been received.

Claim Rejections - 35 USC § 112

6. Claims 1-10, 18, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 1 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

In claim 18: the recitations, "means for targeting the recombinant gene for posttranscriptional gene silencing" and "means for targeting the target gene for posttranscriptional gene silencing" render the claim indefinite. The recitation invokes 35 U.S.C. 112, 6th paragraph. However, the specification does not define all such means that are encompassed by the claim.

7. Claims 1-10 and 16-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 has been amended to recite that the recombinant gene comprises a first region of at least 23 contiguous nucleotides substantially identical with at least 23 contiguous nucleotides of the RNA-silenced locus, and the target gene comprises a region of at least 23 contiguous

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nucleotides that are substantially identical with at least 23 nucleotides of a second region of the recombinant gene. The specification does not provide written descriptive support for “substantially”. The term is NEW MATTER and must be deleted from the claim.

New claim 16 is similar to claim 1, but recites that the recombinant gene comprises a first region consisting essentially of at least 23 contiguous nucleotides that are identical with at least 23 contiguous nucleotides of the RNA-silenced locus, and the target gene comprises a region consisting essentially of at least 23 contiguous nucleotides that are identical with at least 23 nucleotides of a second region of the recombinant gene. The specification does not provide written descriptive support for “consisting essentially of”. The recitation is NEW MATTER and must be deleted from the claim.

New claim 18 is also drawn to a method for obtaining RNA silencing of a target gene in a host, the method comprising introducing a recombinant gene into the host, the host comprising an RNA-silenced locus and the target gene, wherein the RNA-silenced locus comprises a means for targeting the recombinant gene for post-transcriptional gene silencing and the recombinant gene comprises a means for targeting the target gene for posttranscriptional gene silencing. The specification does not provide written descriptive support for "a means for targeting the recombinant gene for post-transcriptional gene silencing", or for "a means for targeting the target gene for posttranscriptional gene silencing". The recitations are NEW MATTER and must be removed from the claim.

8. Claims 1-10 remain and claims 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method when the

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recombinant gene comprises a region of at least 23 nucleotides that are identical to the silenced locus, and when the target gene comprises a region of at least 23 nucleotides that are identical to the recombinant gene, does not reasonably provide enablement for the claimed method when the regions of homology are 23 nucleotides having less than 100% identity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record stated in the Office action mailed August 7, 2007. Applicants traverse in the papers filed February 7, 2007. Applicants' arguments were fully considered but were not found persuasive.

Applicants argue that claim 1 has been amended to recite "first region of at least 23 contiguous nucleotides that identical with at least 23 contiguous nucleotides of the RNA-silenced locus" and "region of at least 23 contiguous nucleotides that are identical with at least 23 contiguous nucleotides of a second region of the recombinant gene." (response, page 9, 2nd full paragraph). However, this is not how claim 1 is amended. The amendment to claim 1 recites, "first region of at least 23 contiguous nucleotides substantially identical with at least 23 contiguous nucleotides of the RNA-silenced locus" and "region of at least 23 contiguous nucleotides that are substantially identical with at least 23 contiguous nucleotides of a second region of the recombinant gene." Because of the term "substantially", the amendment encompasses embodiments where the regions do not comprise at least 23 contiguous nucleotides that are identical. The rejection is maintained.

Claims 18 and 19 are added to the rejection because the specification does not teach all such means that can be used to practice the invention. The specification teaches the method

wherein the recombinant gene comprises a first region of at least 23 nucleotides that are identical with at least 23 contiguous nucleotides of the RNA-silenced locus, and when the target gene comprises a region of at least 23 contiguous nucleotides that are identical with at least 23 contiguous nucleotides of a second region of the recombinant gene. However, the specification does not teach what other means for targeting the recombinant gene and target gene can be used with the claimed method. See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

Claim Rejections - 35 USC § 103

9. Claims 1-10 remain and new claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Houdt et al. (Mol. Gen. Genet., 2000, Vol. 263, pages 995-1002) in combination with Depicker et al. (Curr. Op. Cell Biol., 1997, Vol. 9, pages 373-382), for the reasons of record stated in the Office action mailed August 7, 2007. Applicants traverse in the papers filed February 7, 2007. Applicants’ arguments were fully considered but were not found persuasive.

Applicants argue that where “Van Houdt 1” (Applicants’ nomenclature) silences a gene not previously silenced, silencing occurs by virtue of containing a nptII region homologous to a silenced nptII locus, and thus the recombinant GUS gene has significant homology with a silenced locus and does not meet the recited element of claim 1 (response, page 10, 1st full paragraph). However, this argument addresses Van Houdt 1 alone, and does not address the combination of references as presented in the rejection. One cannot show nonobviousness by

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attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants argue that Depicker teaches that gene silencing may occur *in trans* where the silenced locus has homology to the target sequence, but does not teach a situation wherein the target gene to be silenced has no significant homology to the silenced locus, and therefore does not remedy the lack of teaching of Van Houdt 1 (response, page 10, 1st full paragraph). However, the rejection explains that the target gene does have homology with the region of the recombinant gene that is distinct from the region that has homology with the silenced locus. The rejection explains that it was known in the art that introduction of transgenes into a host plant causes PTGS of a homologous endogene *in trans* in the host. Applicants are arguing that Depicker does not specifically teach a situation wherein the target gene to be silenced has no significant homology to the silenced locus. However, the rejection does explain why this is obvious, as it was known in the prior art that that homology-dependent gene silencing suppresses expression of a homologous gene *in trans*. Further, it is not necessary that a reference actually suggest changes that Applicants made. See *In re Sheckler*, 438 F.2d 999, 1001, 168 USPQ 716, 717 (CCPA 1971).

10. Claims 1-10 remain and new claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Houdt et al. (Plant Physiol., 2003, Vol. 131, pages 245-253), for the reasons of record stated in the Office action mailed August 7, 2007. Applicants traverse in the papers filed February 7, 2007. Applicants' arguments were fully considered but were not found persuasive.

This reference was available as prior art because the claim for priority in the instant application was not perfected. Applicants filed a certified copy of EP 01203760, filed May 10, 2001 and argue that the claim for priority has been perfected (response, page 11, 1st full paragraph). However, the instant application also claims priority to PCT/EP02/11188, filed October 2, 2002, which in turn claims priority to EP 01203760. A certified copy of PCT/EP02/11188 has not been filed. The rejection is maintained.

Summary

11. Claims 1-10 and 14-19 are rejected; non-elected claim 13 remains withdrawn from consideration.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

May 8, 2008

/Ashwin Mehta/
Primary Examiner, Art Unit 1638